

NOTIFICATION PURSUANT TO SECTION 6 OF DSHEA
AND 21 CFR §101.93.

This notification is being filed on behalf of Qualiceutix Inc. which is the distributor (SSI / Kyowa Hakko are the manufacturer) of the product which bears the statements identified in this notification. Its business address is: 56 Greenhayes Avenue, Banstead, Surrey, SM7 2JQ, United Kingdom. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label and labeling the statements appear is (CITICOLINE).

The text of each statement for which notification is now being given is as follows:

SEP 02 2003

- Statement 1: Citcoline helps to raise phosphatidylserine levels, an important component that regulates cell to cell communication.
- Statement 2: Citcoline helps to counteract the effects of the membrane injuring molecules from free radicals.
- Statement 3: Citcoline helps maintain healthy cell membranes in the brain to promote optimum cognitive function.
- Statement 4: Citcoline (sometimes known as CDP-Choline) is a naturally occurring compound which can help maintain brain functions.
- Statement 5: Citcoline as a raw material helps the production of phosphatidylcholine, a major phospholipid component of the brain cell membrane.
- Statement 6: A growing body of research suggests that Citcoline at a dose range between 1000 mg to 2000 mg helps maintain memory, thinking ability and mental functions as we age.

The following summary identifies the dietary ingredient or supplement for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient or Supplement that is the Subject of the Statement</u>
1	Citcoline
2	Citcoline
3	Citcoline
4	Citcoline
5	Citcoline
6	Citcoline

97S 0162

LET

12833

85715

The following identifies the brand name of the supplement for which a statement is made:

Statement Number	Brand Name*	Label/Labeling**
1		
2		
3		
4		
5		
6		

I, (company official), am authorized to certify this Notification on behalf of (company name). I certify that the information presented and contained in this Notification is complete and accurate, that (company name) has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 13th Aug, 2003 By: B Patel 

* If brand name is the same as company name, indicate company name.

** If the statement appears on the product label only, indicate "label." If the statement appears only in literature, ads, website etc., indicate "labeling." If the statement appears on both the label and literature, etc., indicate "label/labeling."

NOTE: Submit one form for each product with ALL statements used for that product.

Send form to:

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Submit signed original plus 2 copies. It must be signed by a responsible individual with the company who is authorized to certify as to the information submitted.

Do not submit copies of label or literature. Submit the form only.

Keep one copy for your records. This should be kept in your substantiation file, which is your file of studies, articles, etc., that substantiate/verify the statements as "truthful and not misleading."